DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-429/S-021

Abbott Laboratories
Hospital Products Division
200 Abbott Park Road, D-389, J45-2
Abbott Park, IL 60064-6157

Attention: Jean Kirkleit Davis
Manager, Regulatory Affairs

Dear Ms. Davis:

Please refer to your supplemental new drug application dated March 20, 2003, received March 21, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aminosyn RF 5.2%.

This supplemental new drug application provides for a revised **PRECAUTIONS** section. A **Geriatric Use** subsection is added in accordance with 21CFR 201.57(f)(10). We note that you have incorporated all the changes that were approved on October 25, 2002, for supplement S-019 (Package Insert, Overwrap Labels, and Immediate Container Labels).

We have completed our review of this supplemental new drug application and it is approved, effective on the date of this letter,

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Victoria Kao, Regulatory Project Manager, at (301) 827-7410.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Acting Director
Division of Anesthetic, Critical Care, and
Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Celia Winchell
6/18/03 01:55:18 PM
for Bob A. Rappaport, M.D., Acting Division Director